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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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06/07/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

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### DETAILED ACTION

1. Applicants' Response to Office Action, received 25 May 2010, is acknowledged.
2. Claims 31, 35, 37 and 40-66 are pending and under consideration.

### Rejections Maintained

3. The rejection of claims 31, 35, 37 and 61-63 under 35 U.S.C. 112, first paragraph, scope of enablement for treatment or prevention of all diseases caused by all agents, is maintained.

Applicants argue that the Examiner seems to require a showing of efficacy of *in vivo* administration of DMBT1.

The examiner has considered applicants' argument, but does not find it persuasive. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The scope of the newly amended instant claims is drawn to treating or preventing all diseases caused by a non-living compound possessing  $\geq 1$  accessible sulphate and/or  $\geq 1$  accessible phosphate group by administration of a therapeutically effective amount of  $\geq 1$  amino acid motif comprising 11 contiguous amino acids derived from a polypeptide comprising SEQ ID NO:1 or of a nucleic acid encoding said amino acid motif.

Example 1 of the instant specification teaches minimal sequence requirements of DMBT1 for *in vitro* binding to Gram-positive and Gram-negative bacteria. Example 2 teaches various ligands which may bind *in vitro* to DMBT1. Example 3 teaches *in vitro* binding to bacterial surface structures by DMBT1. Example 4 teaches that DMBT1 obtained from different donors displayed remarkable differences in *in vitro* binding efficacies for *S. typhimurium*, And differential efficacies in inhibition of HIV infection *in vitro*. Example 5 is proposed applications

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of DMBT1. Example 6 is the generation of mice homozygously deficient for *Dmbt1*. Example 7 teaches various expression patterns DMBT1 in humans. Example 8 teaches that DMBT1-Knockout mice are more susceptible to dextran sulfate sodium. Example 9 proposes implication for DMBT1 use in defense against disease causing agents.

However, the specification does not provide any evidence that the administration of a polypeptide comprising SEQ ID NO:1 or a functional fragment or derivative thereof either treats or prevents all diseases, commensurate with the scope of the instant claims.

Applicants provide a Declaration of Dr. Jan Mollenhauer in support of their argument that supplementation with either the polypeptide or the peptides of the invention can be applied for cancer therapy.

The examiner has considered the Declaration, but does not find it persuasive. As with the instant specification, the Declaration contains no actual *in vivo* administration, but only *in vitro* assays, or observations concerning the absence of DMBT1 in subjects.

Neither the instant specification nor the Declaration provides sufficient support, e.g., doses, routes of administration, levels needed at the site of action, etc. for one of ordinary skill in the art to make and use the inventions commensurate with the extremely broad scope of the instant claims.

### **Conclusion**

4. Claims 31, 35, 37 and 61-63 remain finally rejected.
5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

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If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 3, 2010